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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/696,982	10/27/2000	F. Richard Bringhurst	0609.4430001/JAG/CMB	1728
26111	7590	03/19/2004	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			ULM, JOHN D	
			ART UNIT	PAPER NUMBER

1646

DATE MAILED: 03/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/696,982

Applicant(s)

BRINGHURST ET AL.

Examiner

John D. Ulm

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1) Claims 9 to 23 are pending in the instant application. Claims 10 and 21 to 23 have been amended as requested by Applicant in the correspondence filed 10 November of 2003.

2) A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10 November of 2003 has been entered.

3) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5) Claims 21 to 23 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. These claims are incomplete because they do not recite any steps that reflect or account for the difference, if any, between the u-PA activity of the "cell line which expresses urokinase-type plasminogen activator (u-Pa)" and the "cell line which expresses u-PA and which has inhibited Gs signaling of u-PA activity". These claims appear to refer to four different groups of cells: a first group

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of cells which expresses u-PA activity but has not been exposed to "said compound of interest"; a second set of cells which expresses u-PA, has inhibited Gs signaling of u-PA activity relative to the first set of cells, and has not been exposed to "said compound of interest"; a third group of cells which expresses u-PA activity and which **has** been exposed to "said compound of interest"; and a fourth set of cells which expresses u-PA, has inhibited Gs signaling of u-PA activity relative to the first and third set of cells, and which has also been exposed to "said compound of interest". Whereas the claims appear to require the accumulation of experimental data from each of the four sets of cells recited therein, the analytical steps recited in section "(e)" of claim 21 and section "(f)" in each of claims 22 and 23 do not account for these four sets of data. There claims, therefore, are confusing and incomplete.

6) Claims 21 to 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6.1) Claims 21 to 23 are confusing because the subject matter encompassed by the limitation "a cell line which expresses urokinase-type plasminogen activator (u-Pa)" includes the subject matter encompassed by the limitation "a cell line which expresses u-PA and which has inhibited Gs signaling of u-PA activity". It is not clear that the claim is referring to a first cell line and a second cell line, in which the second cell line has inhibited Gs signaling of u-PA activity relative to the first cell line. Clarification of the relationship between the two cell lines referred to in each of these claims is needed.

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6.2) Claims 21 to 23 are vague and indefinite because there is no antecedent basis for "said cell lines" and "both cell lines". Nothing in these claims, as written, requires two cell lines. A cell line that meets the limitation "which expresses u-PA and which has inhibited Gs signaling of u-PA activity" also meets the limitation "which expresses urokinase-type plasminogen activator (u-Pa)".


6.3) Claim 21 is confusing because of the text "(c) introducing said expression vector into both cell lines of step thereby providing stably transfected cells".

7) Claims 9 to 20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over the Catanzariti et al. publication (BioTechniques 15(3):474-479, Sep. 1993) in view of the combination of the Segre et al. patent (5,494,806) and the Bringhurst et al. publication (Endocrinology 132(5):2090-2098, May 1993) for those reasons of record as applied to claims 2 and 6 to 8 in section 6 of Paper Number 4. Applicant's arguments filed on 10 November of 2003 in traversal of this rejection have been considered but they essentially repeat those arguments of record which have been answered on the record in section 7 of Paper Number 8.

8) Claims 21 to 23, as amended, are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



JOHN ULM
PRIMARY EXAMINER
GROUP 1800

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).